UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/9...	05/2.../97	BEDNARIK	1...

STERNE KESSLER GOLDSTEIN & FOX
1100 NEW YORK AVENUE NW
SUITE 600
WASHINGTON DC 20005-3934

HM11171203

RECEIVED
DEC 18 1998
STERNE, KESSLER, GOLDSTEIN & FOX PLLC

EXAMINER	
DRAPER, G	
ART UNIT	PAPER NUMBER
1646	9

DATE MAILED: 12/03/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on The Election of 7-22-98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 6-65 is/are pending in the application.
Of the above, claim(s) 11-15, 17-19 is/are withdrawn from consideration.
☐ Claim(s) ______ is/are allowed.
☒ Claim(s) 1, 6-10, 16, 20-65 is/are rejected.
☐ Claim(s) ______ is/are objected to.
☐ Claim(s) ______ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on ______ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on ______ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

DOCKETED
Response due March 3, 1999
Stat Bar June 3, 1999

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) ______.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: ______

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 and 9 of 11/97 and 8/98
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

1. ***Restriction Requirement:***

Applicant's election with traverse of Group I, now claims 6-10, 16 and newly added claims 20-65 in Paper No. 8 of 7-22-98 is acknowledged. The traversal is on the ground(s) that even where there is two patentably distinct invention, restriction is improper unless the Examiner can show a serious burden, which applicants contend that the Examiner has not done. This is not found persuasive because most contrary to applicant's position, the written restriction did in fact provide sufficient rationale to support the restriction requirement and establish a serious burden. In fact the scope of the claims directed to the elected Group poses a serious burden on the Examiner to search and examiner each of the various permutations of the nucleotides, fragments and modifications.

The requirement is still deemed proper and is therefore made FINAL.

2. ***Formal Matters:***

Applicants disclosure of related applications by the Assignee is appreciated, but the nature of how related those sequences are in the commonly assigned applications has not been set forth, particularly in view of the fact that these co-pending applications contained several sequences.

It would appear that part of the claimed inventive concept relies on the use of a Deposit, therefore, a copy of the contract and all of the necessary averments is required.

3. ***Objections and Rejections under 35 U.S.C. §112:***

NOTE: It is pointed out that applicant's claims comprise several parts and subparts, and in view of such, it may be difficult for the Examiner to always specifically part out which part and sub-part the rejections apply to. Therefore, in the event some of the rejections inadvertently fail to properly include a claim or part or subpart in the rejection statement, the specific "issue/limitation" that is being rejected in the sub-part will be set forth, and the rejection will further state that any claim which recites such a limitation is also intended to be a part of the rejection.

3a The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-10, 16f, 20(f)-20(l) 20n, 29-34, 37-39, 48, 49(f-g), 59-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6-10, 20f-20k, 29-34, 38-39 and 62-63 are indefinite for failing to adequately describe the percent identity. At pages 8-9, 17, 29 of the specification, applicants set forth different percents ranging from 70% to 99%, but the specification fails to set for a definition for "percent identity", and there are no disclosed methods by which the percent identity is determined; nor are there specific parameters defined. This is relevant because it is known that various different methods will produce different results and different degrees/percents of identity, thus, the skilled artisan would not be able to determine the metes and bounds of the claims for such. It is further clear if the percent identity contemplated by the claims takes into consideration gap, and introns and/or exon that may be present in the sequences that are being compared to that of the instant claims and Seq ID.

Claims 1f, 6-10, 16f, 20l, 20n, 37-39, 49g, 49f, 59-65 and any other claims which refer to the complement are indefinite, ambiguous and confusing and/or are also non-enabling in referring to the complement of the polynucleotides because each of these part refer to a polynucleotide that is defined in terms of an encoded amino acids sequence, but the complement would not be expected to satisfy this limitation. Thus, it is unclear what the scope and/or intent of these claims are.

Claim 48 is indefinite and confusing in the last statement of the claim, namely "any subfragment thereof" because it is not clear if this subfragment is to define the claimed fragment ("said fragment is at least 100 contiguous nucleotides) or if it is intended to define the portions of the various sequences of the enumerated Seq ID No's 5-20. Therefore it is requested that the claim be amended to clarify the intent.

Claim 16 is indefinite and confusing in the proviso statement of " except for at least one to fifty conservative amino acid substitutions" and how this defines or delineate the nucleic acids for the encoded polypeptide.

Claims 20(l) and 49 (f) are indefinite and confusing in stating that first polynucleotide encodes a polypeptide which retains substantially the same activity as the polypeptide of Seq ID No.2, but none of the claims recite any specific activity for the encoded protein, and the use of "substantially" herein, which is a relative terms, further causes the claims to be confusing and/or ambiguous.

3b. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleotide of ID No. 1, does not reasonably provide enablement for: all nucleotide sequences defined by a specific percent identity, for all nucleotides defined by the complement; any 1-50 conservative substitution and any substitutions, deletions and/or additions; the various epitopic regions; and the various nucleotide fragments . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use with a reasonable expectation of success, the invention commensurate in scope with these claims. There are various aspect to this scope/breadth rejection. .

In addition to the fact that the specification has not provided and adequate written description for sequences that are defined with percent identity, the specification has also failed to enable all such sequences, as well as the various fragment or portions of the nucleotide sequence. The specification has taught that the percent identical regions has to cover the coding regions and what useful purpose these regions would have, since these fragments

appear to represent EST sequences. Furthermore, it is not clear if this percent identity has be cover a contiguous regions, or a limited number of contiguous residues over a specific given portion of the encoded protein.

The specification is also non-enabling for the various epitopes of the claims. Although pages 30-33 list these specific regions, the regions specified covers the entire coding regions of the protein. There are not examples or assurances that these regions are antigenic in nature, thus the skilled artisan would be faced with undue experimentation for practicing the invention.

In a similar manner, the specification is also non-enabling for 50 conservative substitution, and the myriad of variant that would be the result of substitution, deletion an/or additions. All that applicants have provided is limited statements at pages 1-17 and Table 1 merely list conservative substitution for the respective amino acids. While it is well settled that a specification need not contain examples in order to be enabling, in the express absence of such, the specification must provide enablement alternatively in the form of evidence or guidance. It is also known and accepted that examples, evidence of guidance are not required if, on its face, it is clear to the skilled artisan that the claims are enabled; and when there is no reason to question the objective truths of applicant's mere statement of assertions that the various polynucleotides of the claims are properly enabled by the specification. However, in addition to there being insufficient examples, the specification is also devoid of sufficient evidence or guidance that would serve to enable this aspect of the claims. The following discussion will serve to establish the Examiner's position for questioning the objective truth.

The specification merely set forth different percent identity, variants, and modification; and have cited general teaching references that appear to merely represent "boiler plate" teaching for how to achieve such modifications. However, what is not taught is the nexus or relation that these would have to the encoded protein since the claims define the polynucleotide in terms of such. For instance, even though applicants have provided the nucleic acid and amino acid sequence for the instant IL-1R AcM, there are no structure/function studies that would lead the

skilled artisan to the regions or specific amino acid residues that can be changed/modified or deleted, with assurance that these polynucleoties encoded for proteins that still possess the desired activity. Furthermore, while some of the claims state that the polynucleotides encode for a polypeptide that has substantially the same activity as the polypeptide of Seq ID No.2, these claims fail to recite any specific activity, as stated above. Again, in the absence of these structure/function studies for the encoded protein, the skilled artisan would not know, absent sufficient examples, evidence or guidance, where to start making the changes; how much change the protein can tolerate without affecting its tertiary and quaternary structure, or biological activity; and whether the change affects the receptor binding region, antigenic epitopes, the enzyme or thermal stability of the polypeptide; or the biological activity and which of the many activities possessed by these encoded proteins would be affected by the change. In view of all of the above, the skilled artisan would encounter undue experimentation to achieve the scope of these claims.

4. *Prior Art Rejections:*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4a Claims 1, 6-10, 16 and 20-65 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chizzonite et al and Greenfeder et al .

Each of the prior art discloses nucleic acid sequences for an protein that appears to 100% identical to that of the claims (see the claims, the figures and sequences). Thus, all of the limitations of the claims are either anticipated or rendered obvious from the prior art, based on the teachings for making and using all or portions of the nucleic acid sequences.

Claims 20, 35-36, 38-49, 58, 62-65 are rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the EST No H80590, T70863 or T85756.

Each of the prior art disclose sequences that are identical to a substantial portion of the nucleotide sequences of the claims (see the listed sequences), therefore, this prior art appears to anticipate and/or render obvious claims which define the nucleotide in terms of hybridization and the various fragments or portions of the claims.

5. ***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1646, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800